



4298 Elysian Fields Avenue
New Orleans, LA 70122

December 5, 1996

WARNING LETTER NO. 97-NOL-18

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Alan D. Hulett
Director
Our Lady of the Lake
Regional Medical Center Blood Bank
5000 Hennessey Boulevard
Baton Rouge, Louisiana 70808

Dear Dr. Hulett:

During an inspection of your hospital blood bank on September 23-27, 1996, our investigators documented violations of Title 21, Code of Federal Regulations (21 CFR), Parts 211 and 606.

Deviations noted included: 1) lack of proper validation of computer system software; 2) failure to establish and implement adequate computer security in allowing software vendor unrestricted modem access and not consistently documenting this access; 3) not conducting a secondary review of computer software modifications; 4) lack of a computer hardware and software change control SOP; and 5) lack of verification that software modifications validated on the "test" system are identical to the modifications implemented later in the "live" system.

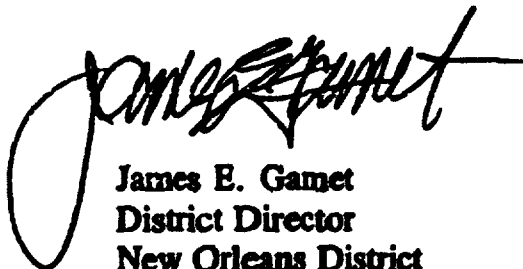
The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility, as Responsible Head, to assure that your establishment is in compliance with all requirements of the Federal regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction.

We acknowledge receipt of your letter dated October 14, 1996, that responded to the deviations noted during the recent inspection. In addition, you should notify this office in writing, within 15 working days of receipt of this letter, of any additional steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Nicole F. Hardin, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122-3848, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Ms. Hardin.

Sincerely,

A handwritten signature in black ink, appearing to read "James E. Gamet", with a large, stylized initial "J" that loops around the first part of the name.

**James E. Gamet
District Director
New Orleans District**

Enclosure: FDA-483

/tjt